



SAFETY DATA SHEET

1. Identification

Product identifier NICODERM CQ

Other means of identification

Synonyms

NICODERM CQ CLEAR PATCH 7MG, 14MG AND 21 MG (US) * NICODERM CQ PATCH 21 MG (US) * NIQUITIN CQ CLEAR PATCH 7 MG, 14 MG AND 21 MG (UK) * NIQUITIN CQ ORIGINAL PATCH 7 MG, 14 MG AND 21 MG (UK) * NICABATE CQ CLEAR PATCH 7 MG, 14 MG AND 21 MG (AUSTRALIA) * NICABATE CQ OPAQUE PATCH 7 MG, 14 MG AND 21 MG (AUSTRALIA) * NICOTINE TRANSDERMAL SYSTEM * NICOTINE, FORMULATED PRODUCT

Recommended use of the chemical and restrictions on use

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
NICOTINE 1-METHYL-2-(3-PYRIDYL) PYRROLIDONE NICOCIDE NICO-FUME L-3-(1-METHYL 1-2-PYRROLIDYL) PYRIDINE BLACK LEAF BETA-PYRIDYL-ALPHA-N-METHYLPYRROLIDINE NICOTINE ALKALOID O-3825 RCRA P075 OHS16430 RTECS QS5250000 3-(N-METHYL-2-PYRROLIDINYL)PYRIDINE 3-(N-METYYLI-2-PYRROLIDINYLI)PYRIDINI	54-11-5	10 - < 12
Other components below reportable levels		80 - < 90

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without medical advice. If ingestion of a large amount does occur, call a poison control centre immediately.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

Symptoms caused by exposure The following adverse effects have been noted with therapeutic use of this material: sweating; salivation; dry mouth; abdominal pain; constipation; vomiting; diarrhoea; headache; dizziness; visual disturbances; tremor; increased heart rate; nervousness; mental impairment; weakness.

Medical attention and special treatment No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
Unsuitable extinguishing media	None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Hazchem Code Not available.

General fire hazards Assume that this product is capable of sustaining combustion.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK Components	Type	Value	Note
NICOTINE (CAS 54-11-5)	15 MIN STEL	200 mcg/m ³	
	8 HR TWA	70 mcg/m ³	
	OHC	3	Reproductive hazard
		3	Skin

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m ³

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m ³

US. ACGIH Threshold Limit Values

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m ³

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
NICOTINE (CAS 54-11-5)	STEL	1.5 mg/m ³
	TWA	0.5 mg/m ³

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Australia OELs: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Patch.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.

Incompatible materials Strong acids. Strong oxidising agents.
Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on possible routes of exposure

Ingestion Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact Health injuries are not known or expected under normal use. May be harmful in contact with skin.
Eye contact Harmful in contact with eyes. Direct contact with eyes may cause temporary irritation.

Symptoms related to exposure The following adverse effects have been noted with therapeutic use of this material: sweating; salivation; dry mouth; constipation; vomiting; abdominal pain; diarrhoea; headache; dizziness; visual disturbances; tremor; increased heart rate; nervousness; mental impairment; weakness.
 NICOTINE nervous system

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful in contact with skin.

Components	Species	Test results
NICOTINE (CAS 54-11-5)		
Acute		
<i>Dermal</i>		
LD50	Rat	140 mg/kg
<i>Oral</i>		
LD50	Rat	188 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Serious eye damage/irritation Harmful in contact with eyes. May be irritating to eyes.

Respiratory or skin sensitisation

Skin sensitisation This product is not expected to cause skin sensitisation.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

NICOTINE

Ames
 Result: negative
 In vitro cytogenetics assay
 Result: negative
 Mouse micronucleus test
 Result: negative
 in vitro micronucleus assay
 Result: positive
 Organ: gingivum
 sister chromatid exchange
 Result: positive

Carcinogenicity Health injuries are not known or expected under normal use.

NICOTINE

Inhalation
 Result: negative
 Species: Rat
 oral
 Result: negative
 Species: Rat
 tumour promotor
 Species: Mouse

Reproductive toxicity Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Specific target organ toxicity - single exposure Nervous system.

Specific target organ toxicity - single exposure

NICOTINE nervous system

Specific target organ toxicity - repeated exposure

NICOTINE Cardiovascular system

Aspiration hazard

Not likely, due to the form of the product.

Other information

Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity

The product contains a substance which may cause long-term adverse effects in the environment. Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test results
NICOTINE (CAS 54-11-5)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia pulex) 0.242 mg/l, 48 hours Static renewal test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss) 4 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

NICOTINE 83.43 % , 28 days, OECD 301 CO2 evol

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

NICOTINE 1.17

Bioconcentration factor (BCF)

NICOTINE 5

Mobility in soil

Not available.

Adsorption

Soil/sediment sorption - log Koc

NICOTINE 2 Estimated

Volatility

Henry's law

NICOTINE 0 atm m³/mol Estimated

Other adverse effects

Not available.

13. Disposal considerations

Disposal methods

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose in accordance with all applicable regulations.

Residual waste

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

IATA

UN number 3077

UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (NICOTINE, FORMULATED PRODUCT)

Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Packing group	III
Environmental hazards	No.
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

UN number	3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NICOTINE, FORMULATED PRODUCT)

Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-F
Special precautions for user	Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

IATA; IMDG



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

NICOTINE (CAS 54-11-5)

applies to all preparations in any concentration Avoid contact with eyes., Avoid contact with skin.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

NICOTINE (CAS 54-11-5)

1 Not to be available except to authorised or licensed persons.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

NICOTINE (CAS 54-11-5)

in preparations for human therapeutic use Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

NICOTINE (CAS 54-11-5)

in preparations, when labelled and packed for the treatment of animals

Australia Medicines & Poisons Schedule 7

NICOTINE (CAS 54-11-5)

Exception may apply, see the regulation for relevance.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date 22-September-2014

Revision date 22-September-2014

References GSK Hazard Determination

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
TOXICOLOGICAL INFORMATION:
Transport Information: Proper Shipping Name/Packing Group
Regulatory Information: United States
GHS: Classification